

- (i) Incentive payments.
- (ii) Provider eligibility determinations.
- (iii) Demonstration of efforts to adopt, implement or upgrade and meaningful use eligibility for incentive payments under this part.

(2) A description of the process in place, and a methodology for verifying such information, to address Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (32 U.S.C. 3729 *et seq.*), and the anti-kickback statute (section 1128B(b) of the Act).

(f) *Optional—proposed alternatives.* A State may choose to propose any of the following, but they must be included as an element in the State Medicaid HIT Plan for review and approval:

(1) An alternative methodology for measuring patient volume, consistent with § 495.306(g).

(2)(i) A revised definition of meaningful use of certified EHR technology consistent with § 495.4 and § 495.316(d)(2) of this part.

(ii) Any revised definition of meaningful use may not require additional functionality beyond that of certified EHR technology and conform with CMS guidance on Stage 1. See also § 495.316(d)(2).

(g) *Optional—signed agreement.* At the State's option, the State may include a signed agreement indicating that the State does all of the following:

(1) Designates CMS to conduct all audits and appeals of eligible hospitals' meaningful use attestations.

(2) Is bound by the audit and appeal findings described in paragraph (g)(1) of this section.

(3) Performs any necessary recoupments if audits (and any subsequent appeals) described in paragraph (g)(1) of this section determine that an eligible hospital was not a meaningful EHR user.

(4) Is liable for any FFP granted to the State to pay eligible hospitals that, upon audit (and any subsequent appeal) are determined not to have been meaningful EHR users.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54162, Sept. 4, 2012]

#### § 495.334 [Reserved]

#### § 495.336 Health information technology planning advance planning document requirements (HIT PAPD).

Each State's HIT PAPD must contain the following:

(a) A statement of need and objective which clearly state the purpose and objectives of the project to be accomplished and the necessity for the project.

(b) A project management plan which addresses the following:

(1) The planning project organization.

(2) Planning activities and deliverables.

(3) State and contractor resource needs.

(4) Planning project procurement activities and schedule.

(c) A specific budget for the planning of the project.

(d) An estimated total project cost and a prospective State and Federal cost distribution, including planning and implementation.

(e) A commitment to submit a HIT implementation advance planning document.

(f) A commitment to conduct and complete activities which will result in the production of the State Medicaid HIT plan that includes conduct of the following activities:

(1) A statewide HIT environmental baseline self-assessment.

(2) An assessment of desired HIT future environment.

(3) Development of benchmarks and transition strategies to move from the current environment to the desired future environment.

(g) A commitment to submit the plan to CMS for approval.

#### § 495.338 Health information technology implementation advance planning document requirements (HIT IAPD).

Each State's HIT IAPD must contain the following:

(a) The results of the activities conducted as a result of the HIT planning advance planning document, including the approved state Medicaid HIT plan.

(b) A statement of needs and objectives.

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(c) A statement of alternative considerations.

(d) A personnel resource statement indicating availability of qualified and adequate staff, including a project director to accomplish the project objectives.

(e) A detailed description of the nature and scope of the activities to be undertaken and the methods to be used to accomplish the project.

(f) The proposed activity schedule for the project.

(g) A proposed budget including a consideration of all HIT implementation advance planning document activity costs, including but not limited to the following:

- (1) The cost to implement and administer incentive payments.
- (2) Procurement or acquisition.
- (3) State personnel.
- (4) Contractor services.
- (5) Hardware, software, and licensing.
- (6) Equipment and supplies.
- (7) Training and outreach.
- (8) Travel.
- (9) Administrative operations.
- (10) Miscellaneous expenses for the project.

(h) An estimate of prospective cost distribution to the various State and Federal funding sources and the proposed procedures for distributing costs including:

- (1) Planned annual payment amounts;
- (2) Total of planned payment amounts; and
- (3) Calendar year of each planned annual payment amount.

(4) A statement setting forth the security and interface requirements to be employed for all State HIT systems, and related systems, and the system failure and disaster recovery procedures available.

#### **§ 495.340 As-needed HIT PAPD update and as-needed HIT IAPD update requirements.**

Each State must submit a HIT PAPD update or a HIT IAPD no later than 60 days after the occurrence of project changes including but not limited to any of the following:

- (a) A projected cost increase of \$100,000 or more.
- (b) A schedule extension of more than 60 days for major milestones.

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(c) A significant change in planning approach or implementation approach, or scope of activities beyond that approved in the HIT planning advance planning document or the HIT implementation advance planning document.

(d) A change in implementation concept or a change to the scope of the project.

(e) A change to the approved cost allocation methodology.

#### **§ 495.342 Annual HIT IAPD requirements.**

Each State is required to submit the HIT IAPD Updates 12 months from the date of the last CMS approved HIT IAPD and must contain the following:

(a) A reference to the approved HIT PAPD/IAPD and all approved changes.

(b) A project activity status which reports the status of the past year's major project tasks and milestones, addressing the degree of completion and tasks/milestones remaining to be completed and discusses past and anticipated problems or delays in meeting target dates in the approved HIT technology PAPD/IAPD and approved changes to it.

(c) A report of all project deliverables completed in the past year and degree of completion for unfinished products.

(d) A project activity schedule for the remainder of the project.

(e) A project expenditure status which consists of a detailed accounting of all expenditures for project development over the past year and an explanation of the differences between projected expenses in the approved HIT PAPD/IAPD and actual expenditures for the past year.

(f) A report of any approved or anticipated changes to the allocation basis in the advance planning document's approved cost methodology.

[75 FR 44565, July 28, 2010, as amended at 77 FR 54162, Sept. 4, 2012]

#### **§ 495.344 Approval of the State Medicaid HIT plan, the HIT PAPD and update, the HIT IAPD and update, and the annual HIT IAPD.**

HHS will not approve the State Medicaid HIT plan, HIT PAPD and update, HIT-IAPD and update, or annual IAPD